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EXAMINER

MELLER, MICHAEL V

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1654

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Paper No. 2

Application Number: 09/902,461
Filing Date: July 10, 2001
Appellant(s): CHEN, YUAN-TSONG

Elizabeth Mata
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 1/8/2004.

(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments After Final*

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

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(6) *Issues*

The appellant's statement of the issues in the brief is correct.

(7) *Grouping of Claims*

Appellant's brief includes a statement that claims 1-9, 11-23 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) *Claims Appealed*

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) *Prior Art of Record*

Fuller et al., European Journal of Biochemistry, vol. 234, 903-909, 1995.

Bijvoet et al., Human Molecular Genetics, vol. 7, no. 11, 1815-1824, 1998.

(10) *Grounds of Rejection*

The following ground(s) of rejection are applicable to the appealed claims:

35 USC 112, second paragraph rejection:

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Claims 1-9 and 11-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, "periodically" is vague and indefinite. If one were to administer a drug periodically when would that be ? Would one administer the drug every hour, every week, every month ? Periodically could be anything. Once in a while, when is that ?

35 USC 102 rejections:

Claims 1-4, 9, 21 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Fuller et al. (ref. AV2)

Fuller teaches that recombinant precursor form of acid alpha glucosidase is administered to a patient to treat Pompe's disease, see abstract, pages 908.

It is noted that since the enzyme is being administered to an individual that it is inherent to that individual that they would suffer from the types of diseases claimed in claims 2-4 since the individuals are not defined in claim 1 as suffering from those specific types of diseases. As stated in Fuller, the claimed enzyme can be administered to a patient since it is clear from their results that it would treat the claimed disease, see page 234, top right column.

35 USC 102/103 rejection:

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Claims 1-7, 11-18, 21 and 23 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Fuller et al.

The teachings of the reference are above. The amounts of enzyme used, the method of administration and the intervals at which the enzyme are used are anticipated or in the very least obvious over the cited references. It is not clearly apparent from the reference if these limitations are present or not, but it is inherent or in the very least obvious to use the amount, methods of administration and intervals claimed.

35 USC 103 rejections:

Claims 1-9 and 11-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bijvoet et al. in view of Fuller et al.

Bijvoet teaches that recombinant human acid alpha glucosidase is administered to a patient to treat Pompe's disease, see abstract, pages 1816, 1819, 1821.

It is noted that since the enzyme is being administered to an individual that it is inherent to that individual that they would suffer from the types of diseases claimed in claims 2-4 since the individuals are not defined in claim 1 as suffering from those specific types of diseases.

Bijvoet does not teach that the enzyme is a precursor of recombinant human acid alpha-glucosidase produced in Chinese hamster ovary cells, the amounts used, the

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interval used to administer the enzyme, to use an immunosuppressant or that instructions are included with the enzyme for administration.

Fuller teaches that the claimed enzyme can be produced in hamster ovary cells.

It would have been obvious that the enzyme is a precursor of recombinant human acid alpha-glucosidase and that Chinese hamster ovary cells were used to produce the claimed enzyme since Fuller teaches that the claimed enzyme can be produced in hamster ovary cells and that the enzyme is a precursor of recombinant human acid alpha-glucosidase since such desirable results are obtained with such an enzyme. Further, it would have been obvious to use an immunosuppressant since such medications are commonly used to suppress the immune system to better administer drugs and the like, reducing the possibility of rejection of the drug by the immune system. To include instructions in with the enzyme is obvious since the enzyme is going to be used for the same purpose as claimed (as taught by the references) thus one would want to know how to administer the enzyme.

The adjustment of particular conventional working conditions (e.g., determining result effective amounts of the enzyme beneficially taught by the cited references, the interval the enzymes are administered, the method of administration of the enzyme, etc., especially within the broad ranges instantly claimed) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Accordingly, this type of modification would have been well within the purview of the skilled artisan and no more than an effort to optimize results.

Claims 1-9 and 11-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fuller et al.

The teachings of the reference are above. The reference does not teach the specific amounts of the enzyme used, the interval used to administer the enzyme, to use an immunosuppressant or that instructions are included with the enzyme for administration.

It would have been obvious to use an immunosuppressant since such medications are commonly used to suppress the immune system to better administer drugs and the like, reducing the possibility of rejection of the drug by the immune system. To include instructions in with the enzyme is obvious since the enzyme is going to be used for the same purpose as claimed (as taught by the references) thus one would want to know how to administer the enzyme.

The adjustment of particular conventional working conditions (e.g., determining result effective amounts of the enzyme beneficially taught by the cited references, the interval the enzymes are administered, the method of administration of the enzyme, etc., especially within the broad ranges instantly claimed) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Accordingly, this type of modification would have been well within the purview of the skilled artisan and no more than an effort to optimize results.

(11) Response to Argument

In the 35 USC 112, second paragraph rejection appellants argue that the enzyme is administered periodically and such a term is well defined in the specification.

Appellants also point the examiner to a dictionary definition. Exhibit A in response to the final rejection they state explains this. Exhibit A states that periodically refers to “from time to time: frequently”. The claims and specification also state that the “periodically” can occur as much as monthly. It would not be understood by one of ordinary skill in the art that frequently would be monthly. One of ordinary skill in the art might understand daily to be frequently, but monthly ? Appellants need to put such frequent terms in the claims and not “periodically” since their own definition from their own exhibit states that periodically is frequent, not once a month.

In the 35 USC 102 rejection over Fuller appellants argue that Fuller does not describe administration to a human of the GAA (the claimed enzyme) to anything other than cells in culture. Appellant also argues that Fuller does not teach administration of the enzyme, GAA, periodically or at an administration level.

First of all, Fuller makes it clear on page 908, top right hand column, that the enzyme is a useful candidate for replacement therapy on GSD II patients. Anyone having skill in the art knowing that the enzyme was successful in treating cells from

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GSD II patients and that Fuller showed that administering the enzyme was successful to correct the storage phenotype (treat the disease) and knowing that Fuller tells them to administer the enzyme in humans would clearly have been lead to treating human administration. There is no reason that one of ordinary skill in the art would not have treated a human with the enzyme knowing that it worked with the same cells from GSD II patients.

As for the use of the enzyme periodically, appellant argues that Fuller does not administer the enzyme periodically. Fuller does discuss enzyme replacement therapy used in patients and anyone reading Fuller would understand that the enzyme when given to a patient would be more than once. Fuller was done in a laboratory and not in a doctor's office. Knowing that enzyme replacement therapy and other forms of administration of enzymes and other pharmaceuticals are routinely done more than once when a doctor administers them would have been clear to one of ordinary skill in the art. Thus, Fuller does teach more than once and at administration levels since treating GSD II as noted by Fuller and enzyme replacement therapy is routinely administered more than once. Thus, it would have been inevitable that the teachings Fuller if administered to a patient as Fuller suggests would have been administered to a patient more than once.

Appellant also argues that Fuller does not describe treatment of the claimed disease. Appellant argues that simply because *in vitro* results are used that one would not use for *in vivo* use.

Such an argument only pertains to generalities only. There is no specific evidence on the record that the *in vitro* cell culture model is not predictive for this disease model.

As to the statements regarding use the enzyme to treat cardiomyopathy the rejection was clear in that if you treat the GSD II once would also inherently be treating the cardiomyopathy because the cardiomyopathy is associated with the GSD II. It is inevitable that when treating the GSD II that cardiomyopathy will also be treated.

In the 35 USC 102/103 rejection using Fuller appellant states that there are unexpected results as demonstrated by the declaration of record.

Fact is, under 35 USC 102 the same disease is treated with the same enzyme. This rejection only adds specific amounts used and appellant has provided no criticality to these amounts. It is already shown on the record that the same enzyme is well known to be used for the same disease and to use amounts not in the reference is simply the choice of the artisan in an effort to optimize the desired results. Since appellant showed no criticality using these specific amounts or demonstrated why one would not have arrived at these results using the teachings of Fuller, the rejection is proper. Further, as known under 35 USC 102/103 rejections, it is inherent or in the very least obvious to change amounts slightly as used in the laboratory for typical research in treating diseases, and since such amounts are routinely used, and no criticality has been shown by appellants in using such amounts.

In the 35 USC 103 rejection using Fuller , appellant argues the same points as presented above.

In the 35 USC 103 rejection with Bijvoet in view of Fuller appellant argues that Bijvoet does not administer the enzyme periodically.

As stated above by the examiner with reference to Fuller which also applies to Bijvoet, Bijvoet clearly teaches that enzyme replacement therapies is known to be given which would involve more than one time doses. The abstract of Bijvoet even teaches that GSD II patients undergo enzyme replacement therapy and the therapeutic potentiation of the enzyme is shown both in vivo and vitro. Thus, anyone reading this would know that they are given a direction to administer this more than once in a human. Further, in a laboratory setting administration is often done once to get results but to a doctor he/she would administer this to a patient more than once. No treatment to treat a disease such as a disease like GSD II could be treated in one dose anyway. Medicines are routinely administered to patients more than once clearly.

Appellant discusses a long felt need in the art but the same disease is being treated in the references with the same enzyme as appellants for the same reasons. There is no reason one of ordinary skill in the art would not administer the claimed enzyme to a human knowing it works in a mouse. Mice are well known models of success in humans. Fuller provides the teaching that shows clear indication that use in a human is desired, see Fuller page 908, top right.

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Once again appellant argues that cardiomyopathy was not treated by Bijvoet but as stated above the rejection was clear in that if you treat the GSD II once would also inherently be treating the cardiomyopathy because the cardiomyopathy is associated with the GSD II. It is inevitable that when treating the GSD II that cardiomyopathy will also be treated. Thus, such an administration is clearly obvious to one of ordinary skill in the art.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,



Michael V. Meller
Primary Examiner
Art Unit 1654


MVM

April 1, 2004

Conferees:

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